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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/549,186	04/13/2000	Gilles Guichard	1487-25	7913

7590 03/18/2003

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EXAMINER

PARKIN, JEFFREY S

8

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 03/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/549,186

Applicant(s)

GUICHARD ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Restriction Requirement

35 U.S.C. § 121

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- a. Group I, claim(s) 1, 10, 13, 14, 15-20, and 25 drawn toward a **test system** for the detection of immune complexes utilizing an **immunoretroid peptide**, classified in class 422, subclass 61.
- b. Group II, claim(s) 2, 3, 6-9, 15-20, and 23, drawn to a **vaccine composition** comprising an immunoretroid peptide and vehicle, classified in class 424, subclass 184.1.
- c. Group III, claim(s) 4 and 22, drawn to a **method of treating an autoimmune disease** by administering an immunoretroid peptide, classified in class 514, subclass 2.
- d. Group IV, claim(s) 5 and 24, drawn to an **antibody** which binds to an immunoretroid peptide, classified in class 530, subclass 387.1.
- e. Group V, claim(s) 10, drawn to an **antigen detection method** utilizing an immunoretroid-specific antibody, classified in class 435, subclass 7.1.
- f. Group VI, claim(s) 11, drawn to a **method for the detection of autoimmune disorders** utilizing a **histone H3** immunoretroid peptide, classified in class 436, subclass 506.
- g. Group VII, claim(s) 11 and 12, drawn to **methods for the detection of autoimmune disorders** utilizing **SSA/Ro** immunoretroid peptides, classified in class 436, subclass 506.
- h. Group VIII, claim(s) 21, drawn to an **antibody detection method** utilizing an immunoretroid peptide, classified in class 435, subclass 7.1.

2. Applicants are hereby advised that claims 15-20 reference a "system" from claim 2. Claim 2 actually references a vaccine composition, not a system. If the claims are truly directed toward a "system", they should be included in Group I. If the claims are directed toward a vaccine composition, they should be included in Group II. Applicants should clearly specify which group the claims belong to in the next reply and amend the claims appropriately.

3. Applicants are further advised that if one of Groups I-V or VIII are selected, a single immunoretroid compound or peptide must also be selected. For instance, if Group I is elected, the precise

chemical structure of the compound of interest should also be clearly identified. Alternatively, if another group is elected (e.g, Group IV), a specific immunoretroid peptide (e.g., aa 277-291 of the SSA/Ro 52 kDa protein) must also be elected. This is **not** a species election requirement but rather a restriction requirement. Each chemical compound or peptide has a unique amino acid sequence and attendant biochemical, immunological, and physical properties and constitutes an independent and distinct invention. Separate searches will also be required for each peptide.

4. The inventions are distinct, each from the other because of the following reasons:

5. Inventions I, II, and IV are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified groups is directed toward a different product (e.g., test kit, vaccine composition, or antibody) with disparate biochemical and immunological properties. Separate searches will be required for each group.

6. Inventions III and V-VIII are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified groups is directed toward a different methodology that employs different scientific reagents (e.g., antibodies, peptides), different protocols, and performs different scientific objectives (e.g., antigen detection, antibody detection, treatment of autoimmune disorders).

7. Inventions I/II/IV and III/VI/VII/VIII are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, none of the identified methodologies require nor use any of the products and systems of Groups I/II/IV.

8. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibody of Group I can be employed in a number

of materially different processes such as affinity purification protocols.

5 9. Inventions I/II and V are all unrelated. Inventions are
unrelated if it can be shown that they are not disclosed as capable
of use together and they have different modes of operation,
different functions, or different effects (M.P.E.P. § 806.04 and §
10 808.01). In the instant case, the identified methodology neither
requires nor uses any of the products and systems of Groups I and
II.

15 Because these inventions are distinct for the reasons given above
and have acquired a separate status in the art as shown by their
different classification, recognized divergent subject matter, and
require separate searches, restriction for examination purposes as
indicated is proper.

20 10. Applicant is advised that the reply to this requirement to be
complete must include an election of the invention to be examined
even though the requirement be traversed (37 C.F.R. § 1.143).
Applicant is also advised that the claims should be amended to
reflect the election, where necessary.

25 11. Applicant is reminded that upon the cancellation of claims to
a non-elected invention, the inventorship must be amended in
compliance with 37 C.F.R. § 1.48(b) if one or more of the currently
named inventors is no longer an inventor of at least one claim
remaining in the application. Any amendment of inventorship must be
30 accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee
required under 37 C.F.R. § 1.17(I).

Correspondence

35 12. The Art Unit location of your application in the Patent and
Trademark Office has changed. To facilitate the correlation of
related papers and documents for this application, all future
correspondence should be directed to **art unit 1648**.

40 13. Correspondence related to this application may be submitted
to Group 1600 by facsimile transmission. The faxing of such papers
must conform with the notice published in the Official Gazette,
1096 OG 30 (November 15, 1989). Official communications should be
directed toward one of the following Group 1600 fax numbers: (703)
308-4242 or (703) 305-3014. Informal communications may be
submitted directly to the Examiner through the following fax
45 number: (703) 308-4426. Applicants are encouraged to notify the
Examiner prior to the submission of such documents to facilitate
their expeditious processing and entry.

14. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

15 March, 2003